

REMARKS

Status of the Claims

Claims 1-28 are pending. In the present Response, claims 17, 18, and 23 are cancelled; claims 1-3, 7, 11, 12, 14-16, 19-22, and 24-27 are amended; and new claims 29-42 are added. Thus, after entry of these amendments, claims 1-16, 19-22, and 24-42 are presented for consideration.

Pursuant to the Office Action, claims 1-28 are rejected under 35 U.S.C. §112, second paragraph. Claims 1-4, 6, 7, 11-14, 16, 17, and 27 are rejected under 35 U.S.C. §102 for allegedly being anticipated by U.S. Patent No. 5,713,891 to Poppas (hereinafter the “‘891 patent”). Claims 1-3, 8, 9, 11-17, 22, 24, 25, 27, and 28 are rejected under 35 U.S.C. §102 for allegedly being anticipated by U.S. Patent No. 5,749,895 to Sawyer *et al.* (hereinafter the “‘895 patent”). Claims 1, 2, 27, and 29 are rejected under 35 U.S.C. §102 for allegedly being anticipated by U.S. Patent No. 5,156,613 to Sawyer, (hereinafter the “‘613 patent”). Applicants respectfully traverse all outstanding objection to the specification and rejections of the claims.

Support for the Claim Amendments

Support for the amendments can be found throughout the specification, in general. In particular, the claims have been amended to more particularly describe the claimed invention, support can be found, *inter alia*, at page 8, lines 19 to 24; page 11, lines 11-16; and page 22, lines 16-18. Support for new claims drawn to ranges of the proteinaceous substance can be found, *inter alia*, at page 7, lines 25-31, and in the examples. Support for new claims 36-38 drawn to the temperatures and methods of denaturing the solder can be found, *inter alia*, at page 8, lines 27-31; and page 14, lines 5-34. Support for new claims 38-41 can be found, *inter alia*, at page 6, line 27, to page 7, line 18. Support for new claim 42 can be found, *inter alia*, at page 11, lines 17-18. Applicants respectfully submit that no new matter is introduced by the instant amendments.

Objection to the Specification

The Patent Office objects to the Abstract for using the terminology/phraseology "e.g.," citing MPEP 608.01(b). Applicants note that the MPEP section is a section describing the requirement for an Abstract. Applicants were unable to find a section that would make using such terminology objectionable. However, to expedite prosecution, Applicants have amended the Abstract. Applicants submit that no new matter is introduced by the instant amendment.

Issues under 35 U.S.C. §112, second paragraph

Claims 1-28 are rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The Patent Office alleges that claim 1 is indefinite because the phrase "which are denatured" is a prophetic statement. Applicants have amended claim 1 rendering this rejection moot.

The Patent Office alleges that claim 1, 11, 17, and 19 are indefinite for the recitation of the phrase "substantially solid solder." Applicants have amended claims 1, 11, 17, and 19 to obviate this rejection. Applicants submit that, as amended, the claimed composition has a defined shape. Applicants submit that this was the meaning of the phrase "substantially solid solder." Accordingly, the claims have been amended to clarify the scope of the claims, and the amendments do not narrow the scope of the claims.

The Patent Office alleges that claims 6 and 7 are indefinite for lacking antecedent basis in claim 1 for the recitation of "an adjuvant" in claim 1. Similarly, the patent Office alleges that claims 8 and 9 lack antecedent basis in claim 1 for the recitation of "a material;" claims 19-21 lack antecedent basis in claim 11 for the recitation of "a dye;" claims 23-25 lack antecedent basis in claim 11 for the recitation of "shaping;" and claim 26 lacks antecedent basis in claim 11 for the recitation of "sterilizing." Applicants respectfully submit that claims 1 and 11 are broad independent claims and that claims 6-9, 19-21, and 23-26 are dependent claims that further limit

the claimed invention by introducing additional elements. In other words, the dependent claims are directed to different embodiments of the claimed invention. The structural elements are properly introduced by an indefinite article; accordingly, Applicants respectfully submit that the additional elements are properly introduced, there being no issue with antecedent basis.

Issues under 35 U.S.C. §102

Claims 1-4, 6, 7, 11-14, 16, 17, and 27 are rejected under 35 U.S.C. §102(a) for allegedly being anticipated by the '891 patent.

The legal standard for anticipation under 35 U.S.C. §102 is one of strict identity. To anticipate a claim, a single prior source must contain each and every limitation of the claimed invention.

The '891 patent describes a solder that is applied as a dry powder or as a solution (see column 5, lines 9-13, of the '891 patent). The solder is administered at the time of welding, either by brushing, spraying, dripping, or other means known to those skilled in the art (see column 6, line 66, to column 7, line 1, of the '891 patent). It is noted that all the methods for applying the solder that are described are consistent with the solder being in a powder or solution form.

In contrast, Applicants' claimed invention is a solder having a predetermined shape. In other words, Applicants' claimed invention is not in a powder or solution form as taught in the '891 patent. The '891 patent does not teach a solder having a predetermined shape. Accordingly, Applicants respectfully submit that the '891 patent does not teach each and every limitation of the claimed invention. Therefore, the rejection of claims 1-4, 6, 7, 11-14, 16, 17, and 27 under 35 U.S.C. §102(a) may properly be withdrawn.

Claims 1-3, 8, 9, 11-17, 22, 24, 25, 27, and 28 are rejected under 35 U.S.C. §102(a) for allegedly being anticipated by the '895 patent. The '895 patent describes a mechanical support to be used to join, repair or fuse biological materials. In particular, the '895 patent describes denaturing collagen to a gelatin for use in a patch to preshrink the collagen film and prevent

curling of the film upon heating. Applicants note that gelatin forms thermally reversible gels with water and the gel melting temperature is less than about 35°C. This, of course, is below body temperature. Hence, rather than reducing solubility of the solder, the collagen treatment taught by the '895 patent increases solubility of the solder in physiological fluid at body temperature (see column 5, lines 31-37, of the '613 patent to which the '895 patent claims priority).

This is in direct contrast to the instant claimed invention, which is a solder that includes a proteinaceous substance that is partially denatured to maintain the shape of the solder and to reduce its solubility in physiological fluids at body temperature. As noted above, the collagen patch described above is denatured into a gelatin whose solubility is increased in physiological fluid at body temperature. Accordingly, because the '895 patent does not teach each and every element of the claimed invention, Applicants respectfully submit that the rejection of claims 1-3, 8, 9, 11-17, 22, 24, 25, 27, and 28 under 35 U.S.C. §102(a) may properly be withdrawn.

Claims 1, 2, 27, and 28 are rejected under 35 U.S.C. §102(b) for allegedly being anticipated by the '613 patent. The '613 patent describes methods for denaturing or melting collagen filler material and adjacent biological tissue to cause mixing of the denatured or melted collagen and biological tissue to join or reconstruct the tissue (see column 2, lines 23-31, of the '613 patent). The collagen filler material is denatured or melted to act as a type of "biological glue" (see column 3, lines 32-47, of the '613 patent). Therefore, the collagen is only denatured or melted at the time the collagen is being used to join together the biological tissues.

The '613 patent does not teach a solder having a proteinaceous substance that is partially denatured to maintain its predetermined form, *i.e.* the '613 patent does not teach a solder that contains partially denatured proteinaceous substances. It only teaches denaturing to join the pieces of biological tissue together. Accordingly, Applicants submit that the '613 patent does not teach each and every element of the claimed invention. Therefore, Applicants respectfully submit that the rejection of claims 1, 2, 27, and 28 under 35 U.S.C. §102(b) may properly be withdrawn.

CONCLUSION

Applicants request that the Examiner reconsider the application and claims in light of the foregoing reasons and amendments and respectfully submit that the claims are in condition for allowance.

If, in the Examiner's opinion, a telephonic interview would expedite the favorable prosecution of the present application, the undersigned attorney would welcome the opportunity to discuss any outstanding issues and to work with the Examiner toward placing the application in condition for allowance.

Applicants herewith authorize the Commissioner to draft the deposit account to pay for the excess claims fee and the extension of time fee. Applicants believe that no additional fees are necessitated by the present Response. However, in the event any such fees are due, the Commissioner is hereby authorized to charge those fees to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 2/28/2003



Mi K. Kim
Reg. No. 44,830

Fish & Richardson P.C.
4350 La Jolla Village Drive, Suite 500
San Diego, California 92122
Telephone: (858) 678-5070
Facsimile: (858) 678-5099